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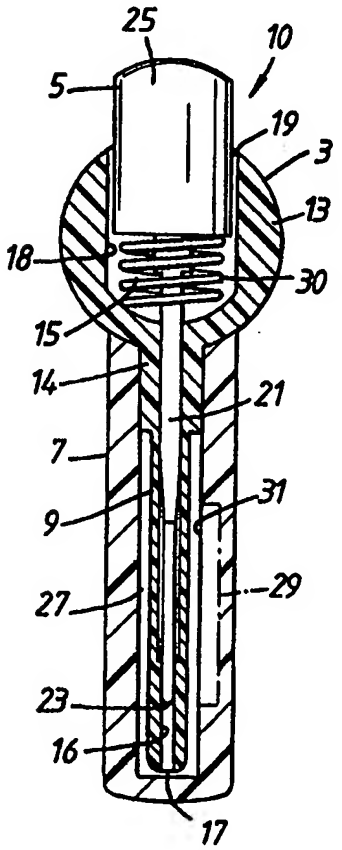
(54) Title: A TRANSURETHRAL DEVICE

(57) Abstract

A transurethral device (10) for delivery of a drug to the urethra of a human or animal body comprising a drug carrying element (3) which presents an elongate shaft (9) having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel (15) having an opening (17) in the outer surface of the elongate shaft for transport of the drug to the urethra. The device further comprises means (5, 30) adapted to draw a dose of the drug into the channel from a fluid supply of the drug. The device may further comprise a sheath (7) for releasably sheathing at least the insertable length of the elongate shaft of the drug carrying element prior to insertion thereof into the urethra of the human or animal body in which case the fluid supply of the drug can conveniently be carried in the sheath.



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A TRANSURETHRAL DEVICE

The present invention relates to a transurethral device for delivery of a drug to the urethra of a human or animal body comprising a drug carrying element which presents an elongate shaft having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel having an opening in the outer surface of the elongate shaft for transport of the drug to the urethra, and is particularly, although not exclusively, concerned with a transurethral device of the aforementioned type for use in the treatment of erectile dysfunction such as impotence, priapism and Peyronie's disease in living male human or animal bodies.

Impotence in living male human bodies is the condition in which a male human body is unable to attain or sustain an erect penis for the satisfactory engagement of sexual intercourse. There are numerous documented causes for impotence, for example impotence caused by vasculogenic disorders such as insufficient blood flow to the arteries in the penis or excessive venal outflow. One aspect of the present invention is directed to erectile dysfunction such as impotence which is treatable by the local application of an erectile dysfunction treatment drug such as an impotence treatment drug to the urethra.

Prior International patent application publications WO95/26158 and WO96/28142 make known various types of transurethral device for treating erectile dysfunction such as impotence, priapism and Peyronie's disease in a living male human body by delivering an erectile dysfunction treatment drug into the urethra of the male human body. For example, WO95/26158 and WO96/28142 make known transurethral devices which comprise a transurethral insertion element having a drug carrying component part and a plunger component part movable in the drug carrying part. The drug carrying component part comprises an elongate shaft portion for insertion into the urethra of the male human body and a handle portion which is connected to the rear end of the shaft portion. In some cases a sheath is provided for sheathing the insertable portion of the elongate shaft.

In one such transurethral device the drug carrying component part is provided with an open-ended axial bore which comprises a rearward section of a first width which passes through the handle portion and a forward section of a second width less than the first width which passes through the elongate shaft. The device is pre-assembled with the erectile dysfunction treatment agent, typically in the form of a solid pellet, in place in the forward section of the axial bore in the drug carrying part.

The plunger component part comprises an enlarged head portion and an elongate shaft portion which projects forwardly from the enlarged head portion. The plunger component part is adapted to be inserted forwardly into the bore in the drug carrying component part to a withdrawn position in which the enlarged head portion is partially located in the rearward section of the bore such that a rearward section of the enlarged head portion projects rearwardly from the bore and the elongate shaft portion projects forwardly into the forward section of the axial bore such that the free forward end of the elongate shaft portion is spaced rearwardly of the erectile dysfunction treatment drug.

A sheath is provided for this device which comprises an elongate main body having axially spaced front and rear faces and which is provided with an elongate recess which extends forwardly from an open end in the rear face to a position intermediate the rear and forward faces. The elongate shaft portion of the drug carrying component part is releasably receivable in the recess presented by the sheath to protect the elongate shaft portion from structural damage and/or contamination prior to insertion thereof into the urethra of the male human body.

In use, the user holds the handle of the drug carrying component part in his fingers and removes the sheath to reveal the elongate shaft portion of the drug carrying component part. The elongate shaft portion of the drug carrying component is then inserted into the urethra of the user and the plunger component part depressed forwardly from the withdrawn position into the drug carrying component part to cause the free forward end of the elongate shaft of the plunger component part to discharge the erectile dysfunction

treatment drug forwardly from the axial bore in the drug carrying component part into the urethra.

In an alternative transurethral device the axial bore in the drug carrying component is capped-off with a flexible membrane to the rearward face of which the forward end of the plunger component part is attached. Forward movement of the plunger component part causes the membrane to present a convex surface over the forward opening of the axial bore in the drug carrying component part to enable an erectile dysfunction treatment agent in the form of a suppository to be received thereon. Rearward movement of the plunger component part draws the membrane into the bounds of the axial bore in the drug carrying component part and causes the membrane to change to a concave configuration around the suppository to secure the suppository to the drug carrying component part. In use, the elongate shaft of the drug carrying component part is inserted into the urethra and the plunger component part moved forwardly to release the suppository into the urethra.

While the aforementioned prior transurethral devices successfully provide for the delivery of an erectile dysfunction treatment drug for, for example, the attainment and sustainment of a penile erection in the case of impotence, Applicants have identified several areas in which such devices suffer drawbacks.

First, the devices are pre-assembled with the erectile dysfunction treatment agent in place in the drug carrying component part. This complicates the overall manufacturing process for the devices and counts against the devices being reused.

Second, the devices are site specific in their delivery of the treatment agent in the urethra. This concentration of the treatment agent in a specific location or site in the urethra can lead to pain being experienced by the patient.

Third, to facilitate insertion of the elongate shaft portion of the drug carrying component part of the previously proposed transurethral devices it is recommended that before insertion of the elongate shaft portion of the drug carrying component part into the urethra

the user first pass urine to wet the urethra. Clearly this is not always practical. Avoidance of this step, however, can obviously lead to pain on insertion of the elongate shaft portion of the drug carrying component part into the urethra. Alternately, the user can be provided with a separate supply of lubricant for application to the outer surface of the elongate shaft of the drug carrying component part of the transurethral insertion element after unsheathing thereof. Again, this is not always convenient or practical and moreover the lubricant tends to end up on the hands and clothes of the user. More importantly, this additional step introduces the possibility of contamination of the elongate shaft portion of the drug carrying component part of the transurethral insertion element.

The present invention proposes to deal with the aforementioned drawbacks of the prior art.

According to a first aspect of the invention there is provided a transurethral device for delivery of a drug to the urethra of a human or animal body comprising a drug carrying element which presents an elongate shaft having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel having an opening in the outer surface of the elongate shaft for transport of the drug into the urethra, characterised in that the device further comprises means adapted for drawing a metered dose of the drug into the channel in the elongate shaft from a fluid supply of the drug. For convenience, the device may further comprise a sheath for sheathing at least the insertable length of the elongate shaft with the fluid supply of the drug being contained in the sheath. The sheath acts to reduce the risk of contamination of the shaft prior to use of the device and enables the drug to be drawn into the channel of the elongate shaft just prior to use of the device, the drug carrying element then being withdrawn from the sheath for delivery of the drug to the urethra.

By "insertable length" is meant the length of the elongate shaft which is to be inserted into the urethra.

According to a second aspect of the invention there is provided a transurethral device for delivery of a drug to the urethra of a human or animal body comprising a drug carrying

element which presents an elongate shaft having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel having an opening in the outer surface of the elongate shaft for transport of the drug into the urethra, and a sheath for sheathing at least the insertable length of the elongate shaft, characterised in that the device further comprises means adapted for drawing the drug into the channel in the elongate shaft from a fluid supply of the drug and that the sheath contains the fluid supply of the drug.

In an embodiment of the invention according to its first and second aspects said means adapted for drawing the drug into the channel in the elongate shaft comprises plunger means adapted to move in the channel between a rearward position and a forward position and biasing means for biasing the plunger means to the rearward position, the plunger means being movable forwardly from the rearward position to the forward position against the biasing action of the biasing means upon application of a predetermined condition to the plunger means with removal of the predetermined condition after the plunger means has been moved forwardly from the rearward position against the biasing action of the biasing means causing the plunger means to be biased back to the rearward position by the biasing means whereby the drug is able to be drawn into the channel in the elongate shaft through the opening when the elongate shaft is dipped in the fluid supply of the drug to a level above the opening.

According to a third aspect of the invention there is provided a transurethral device for delivery of a drug into the urethra of a human or animal body comprising a drug carrying element which presents an elongate shaft having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel having an opening in the outer surface of the elongate shaft, and plunger means adapted to move in the channel between a rearward position and a forward position characterised in that the device further comprises biasing means for biasing the plunger means to the rearward position, the plunger means being movable forwardly from the rearward position to the forward position against the biasing action of the biasing means upon application of a predetermined condition to the plunger means with removal of

the predetermined condition after the plunger means has been moved forwardly from the rearward position against the biasing action of the biasing means causing the plunger means to be biased back to the rearward position by the biasing means whereby the drug is able to be drawn into the channel in the elongate shaft through the opening for transport of the drug into the urethra when the elongate shaft is dipped in a fluid supply of the drug to a level above the opening. For convenience, the device may further comprise a sheath for sheathing at least the insertable length of the elongate shaft with the fluid supply of the drug being contained in the sheath. The sheath acts to reduce the risk of contamination of the shaft prior to use of the device and enables the drug to be drawn into the channel of the elongate shaft just prior to use of the device, the drug carrying element then being withdrawn from the sheath for delivery of the drug to the urethra.

In an embodiment of the invention the fluid supply of drug in the sheath is so arranged in the sheath that at least a substantial portion of the outer surface of the insertable length of the elongate shaft is able to be coated with the drug prior to insertion into the urethra. A better distribution of the drug in the urethra is thus obtained as compared to the case where only the drug dose carried in the channel in the elongate shaft is delivered. Preferably, the drug has lubricating properties so as to facilitate insertion of the elongate shaft into the urethra. For example, the drug is so selected as to have inherent lubricating properties, for example the drug may comprise a therapeutic agent selected from the group consisting of the alfa-2 receptor antagonist Atipamezole, nitrates, long- and short-acting α blockers, calcium blockers, ergot alkaloids, chloropromazine, haloperidol, yohimbine, natural and synthetic vasoactive prostaglandins and their analogs, vasoactive intestinal peptides, dopamine agonists, opioid antagonists, sildenafil, prazosin, alprostadil or mixtures thereof where the device is to treat erectile dysfunction such as impotence, or include a lubricant component, for example cellulose.

In an embodiment of the invention the plunger means is movable forwardly against the biasing action of the biasing means on application of a predetermined force thereto.

In an embodiment of the invention the opening is a forward opening in the free forward end of the elongate shaft, the drug carrying element has a rearward end and the channel extends between the forward opening and a rearward opening in the rearward end of the drug carrying element. In this case it is therefore convenient for the plunger means to be a plunger element which extends forwardly into the channel from the rearward opening.

In an embodiment of the invention the channel is stepped into a forward section of a first diameter which extends rearwardly from the forward opening and a rearward section of a second diameter greater than the first diameter which extends forwardly from the rearward opening and the plunger element comprises a rearward section adapted to slidingly fit in the rearward section of the channel such that in the rearward position of the plunger element the rearward end of the plunger element rearward section protrudes from the rearward opening of the channel and the forward end of the plunger element rearward section is disposed in the rearward section spaced rearwardly from the shoulder between the forward and rearward sections of the channel and a forward section which extends forwardly from the forward end of the plunger element rearward section into the forward section of the channel. The predetermined force is thus able to be applied to the protruding part of the plunger element to move the plunger element forwardly against the biasing action of the biasing means.

In an embodiment of the invention the biasing means is a resilient member positioned between the forward end of the plunger element rearward section and the shoulder between the rearward and forward sections of the channel, the resilient member being compressed on forward movement of the plunger element in the channel. The resilient member may be a spring.

In an embodiment of the invention the forward end of the plunger element rearward section abuts the shoulder between the rearward and forward sections of the channel in the forward position of the plunger element. Alternately, in the forward position of the plunger element the forward end of the plunger element rearward section is prevented from any further appreciable forward movement by the resilient member. These delimiting features in

combination with selection of biasing means of a predetermined biasing action enables a predetermined metered dose of the drug to be drawn into the channel in the elongate shaft.

For a compact construction of the device forward movement of the plunger element against the biasing action of the biasing means when the drug has been drawn into the channel causes the drug to be ejected from the forward opening. There is therefore no need for the device to be provided with separate drug ejection means.

The transurethral device in accordance with the invention is particularly, although not exclusively, for use in the delivery of an erectile dysfunction treatment drug to the urethra of a living male human or animal body, for example an impotence treatment drug.

According to a fourth aspect of the invention there is provided a method of incorporating a drug into a transurethral device for delivery of the drug to the urethra of a human or animal body, the transurethral device comprising a drug carrying element which presents an elongate shaft having a free forward end for insertion into the urethra of the human or animal body in a forward direction and a channel having an opening in the outer surface of the elongate shaft for transport of the drug to the urethra, characterised by the step of providing a fluid supply of the drug, dipping the elongate shaft into the fluid supply to a level above the opening of the channel and drawing a dose of the drug into the channel in the elongate shaft through the opening. Ideally, the device is provided with means for drawing the dose of the drug into the channel from the fluid supply. The transurethral device may be a device according to the invention.

By way of example an embodiment of the present invention will now be described with reference to the accompanying Figure which is a side cross-sectional view of an assembled transurethral device 10 for treating erectile dysfunction such as impotence in a male human patient or body. The transurethral device 10 comprises a transurethral insertion element for insertion in the urethra of the male human body having a drug carrying part 3 and a plunger part 5 and a sheath 7 for storage of the transurethral insertion element prior to use thereof.

Preferably, the parts of the transurethral device 10 are moulded as one-piece bodies from a plastics material.

The drug carrying part 3 presents an elongate shaft 9 having a free forward end adapted to be insertable into the urethra of the male human body, a finger grip 13 for the male human body to hold the transurethral insertion element and a collar 14 which connects the forward end of the finger grip 13 to the rear end of the elongate shaft 9. An axial bore 15 extends through the drug carrying part 3 between a forward open end 17 at the forward end of the elongate shaft 9 and a rear open end 19 in the rear end of the finger grip 13. The bore 15 is stepped into a forward section 16 of a first width which extends rearwardly from the forward open end 17 through the elongate shaft 9 and a rearward section 18 of a second width which is greater than the first width which extends forwardly from the rear open end 19 through the finger grip 13. The forward section 16 of the bore 15 is adapted in use to carry an erectile dysfunction treatment drug which is to be transferred to the urethra of the male human body by the plunger part 5 as hereinafter to be described.

The plunger part 5 of the transurethral insertion element presents an elongate shaft 21 having a free forward end 23 and an enlarged head 25 connected to the rear end of the elongate shaft 21. When the transurethral insertion element is assembled the elongate shaft 21 and enlarged head 25 of the plunger part 5 are respectively received in the forward section 16 and rearward section 18 of the bore 15 in the drug carrying part 3.

The sheath 7 is provided with a bore 27 sized to releasably receive the elongate shaft 9 and collar 14 of the drug carrying part 3 until such time as the transurethral insertion element is to be used. The elongate shaft 9 is thus kept free from damage and/or contamination. The sheath 7 is further provided with a fluid supply of the erectile dysfunction drug (not shown) such that the drug surrounds substantially all of the elongate shaft 9 when sheathed. The collar 14 of the drug carrying part 3 acts as a sealing ring to prevent leakage of the drug from the bore 27 of the sheath 7. The drug has a composition which comprises a therapeutic agent for treating erectile dysfunction and, for example, one or more carriers and/or enhancers for the therapeutic agent.

While it is shown that the whole of the elongate shaft 9 of the drug carrying part 3 is sheathed in the sheath 7 it will be appreciated by those versed in the art that if the length of the elongate shaft 9 is longer than that portion to be inserted into the urethra then it is sufficient that just this insertable length be sheathed.

The transurethral insertion element further comprises biasing means in the form of a spring 30 between the forward end of the enlarged head 25 of the plunger part 5 and the step between the forward and rearward sections 16, 18 of the bore 15 through the drug carrying part 3. The spring 30 acts to bias the plunger part 5 rearwardly to a withdrawn position as shown. Application of a finger pressure to the enlarged head 25 enables the plunger part 5 to be depressed forwardly against the biasing action of the spring 30.

Release or relaxation of the finger pressure on the enlarged head 25 causes the plunger part 5 to be returned to the withdrawn position by the spring 30. The effect of this reciprocal movement of the plunger part 5 is to generate a pressure at the forward open end 17 of the bore 15 in the drug carrying part 3 which draws a dose of the drug in the fluid supply thereof into the bore 15 through the forward open end 17.

By selecting a spring of a predetermined biasing strength a metered dose of the drug can be drawn into the bore 15 in the drug carrying part 3 by delimiting the forward movement of the plunger part 5, that is, the plunger part 5 would be depressed forwardly from the withdrawn position as far as possible against the action of the spring 30 before release. Alternately, or in addition, a metered dose can be drawn into the bore 15 in the drug carrying part 3 by so constructing and arranging the transurethral insertion element such that depressing the plunger part 5 sufficiently forwardly causes the forward end of the enlarged head 25 to abut the step between the forward and rearward sections 16, 18 of the bore 15 in the drug carrying part 3. The device 10 is set up so as to draw in a dose of the drug of up to 100 mg, for example 50 mg, with the dosage comprising a therapeutically effective amount of the therapeutic agent which values are known in the art. As an example, therapeutically effective amounts for various erectile dysfunction therapeutic

agents are given in WO95/26158 and WO96/28142. Of course, the parameters of the device such as the properties of the spring 30 and hence the return distance of the plunger part 5 can be customised to draw in a different metered dose of the drug.

Once the drug has been drawn into the bore 15 through the forward open end 17 as aforesaid the transurethral insertion element is withdrawn from the sheath 7 for insertion into the urethra of the male body. Withdrawal of the transurethral insertion element from the sheath 7 results in the outer surface of the elongate shaft 9 of the drug carrying part 3 additionally becoming coated with the drug.

The elongate shaft 9 of the drug carrying part 3 of the transurethral insertion element is then inserted into the urethra of the male body and the plunger part 5 depressed forwardly to transfer the drug from the bore 15 to the urethra through the forward open end 17.

This arrangement leads to a more uniform distribution of the drug on the walls of the urethra as compared to the case if only the drug in the bore 15 were delivered to the urethra because the drug coated on the elongate shaft 9 is transferred to the urethra wall rearward of the delivery site for the drug in the bore 15. The metered dose of the drug drawn into the bore 15 of the elongate shaft 9 or the concentration of the therapeutic agent in the drug can be tailored if need be to take account of this additional source of drug administered to the urethra to ensure that an acceptable collective amount of the therapeutic agent is administered by the two different administration mechanisms employed by the device 10.

Advantageously, the drug used has lubricating properties. Insertion of the elongate shaft 9 into the urethra is thus facilitated by the drug coating thereon having lubricating properties. This can be achieved by selecting a drug having inherent lubricating properties or by forming the drug with a lubricant. Where the transurethral device 10 is to deliver an erectile dysfunction treatment drug such as an impotence treatment drug the alfa-2 antagonist Atipamezole (Orion Farmos), nitrates, long- and short-acting α blockers, calcium blockers, ergot alkaloids, chloropromazine, haloperidol, yohimbine, natural and synthetic vasoactive prostaglandins and their analogs, vasoactive intestinal peptides,

dopamine agonists, opioid antagonists, sildenafil ("Viagra" sold by Pfizer), prazosin, alprostadil or mixtures thereof may be mentioned as therapeutic agents or therapeutic agent mixtures having inherent lubricating properties which could form a part of the composition of the drug. Alternately, a cellulose may be mentioned as a suitable lubricant for inclusion in the composition of the drug.

Rather than simply filling the bore 27 of the sheath 7 with a fluid supply of the drug the sheath 7 may instead be provided with a drug containing compartment 29. As can be seen, a boundary wall 31 of the drug containing compartment 29 also serves as a portion of the boundary wall of the bore 27 in the sheath 7. The common boundary wall 31 is constructed so as to be rupturable or otherwise openable on application of a predetermined condition thereto, in this case a predetermined pressure being applied to the outer surface of the sheath 7 which when transmitted to the common boundary wall 31 causes the common boundary wall 31 to be brought to an open disposition. Bringing the common boundary wall 31 to the open disposition results in the drug being able to be discharged from the compartment 29 into the bore 27 in the sheath 7 and onto the adjacent outer surface of the elongate shaft 9 of the drug carrying part 3.

The drug can be coated over the whole of the outer surface of the elongate shaft 9 of the drug carrying part 3 by manipulation of the transurethral insertion element relative to the sheath 7. The collar 14 of the drug carrying part 3 again acts as a sealing ring to prevent leakage of the drug from the bore 27 of the sheath 7. Alternatively, the drug containing compartment 29 can be so dimensioned and juxtaposed to the bore 27 in the sheath 7 that discharge of the drug from the compartment 29 automatically coats the elongate shaft 9 of the drug carrying part 3 bounded by the bore 27. For example, the drug containing compartment 29 could be formed so as to bound substantially all of the bore adjacent the elongate shaft 9 of the drug carrying part 3.

While it is preferable that substantially all of the insertable length of the elongate shaft 9 of the drug carrying part 3 be coated, insertion of the elongate shaft 9 into the urethra of the

male human body will still be more comfortable even if only a part of the insertable length is coated, for example a forward section of the elongate shaft 9.

It can therefore be seen that the present invention provides a transurethral device that is simple to fill with a dose of drug. The present invention also solves the problem of the general requirement to keep the prior art devices which use an erectile dysfunction treatment drug in the form of a solid pellet or suppository cool to compensate for the heat sensitivity of the drug form and the difficulty in dispensing the drug form if it softens. Moreover, the present invention provides a transurethral device which may be reused. Embodiments of the invention, such as those described herein with reference to the accompanying Figures of drawings, are additionally easier to insert into the urethra and deliver a more uniform distribution of the drug into the urethra when compared to prior art devices.

Claims:

1. A transurethral device (10) for delivery of a drug to the urethra of a human or animal body comprising a drug carrying element (3) which presents an elongate shaft (9) having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel (15) having an opening (17) in the outer surface of the elongate shaft for transport of the drug into the urethra, characterised in that the device further comprises means (5, 30) adapted for drawing a metered dose of the drug into the channel in the elongate shaft from a fluid supply of the drug.

2. A transurethral device as claimed in claim 1, characterised in that the device further comprises a sheath (7) for sheathing at least the insertable length of the elongate shaft and that the fluid supply of the drug is contained in the sheath.

3. A transurethral device (10) for delivery of a drug to the urethra of a human or animal body comprising a drug carrying element (3) which presents an elongate shaft (9) having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel (15) having an opening (17) in the outer surface of the elongate shaft for transport of the drug into the urethra, and a sheath (7) for sheathing at least the insertable length of the elongate shaft, characterised in that the device further comprises means (5, 30) adapted for drawing the drug into the channel in the elongate shaft from a fluid supply of the drug and that the sheath contains the fluid supply of the drug.

4. A transurethral device as claimed in claim 1, 2 or 3, characterised in that said means adapted for drawing the drug into the channel in the elongate shaft comprises plunger means (5) adapted to move in the channel between a rearward position and a forward position and biasing means (30) for biasing the plunger means to the rearward position, wherein the plunger means is movable forwardly from the rearward position to the forward position against the biasing action of the biasing means upon application of a

predetermined condition to the plunger means and wherein removal of the predetermined condition after the plunger means has been moved forwardly from the rearward position against the biasing action of the biasing means causes the plunger means to be biased back to the rearward position by the biasing means whereby the drug is able to be drawn into the channel in the elongate shaft through the opening when the elongate shaft is dipped in the fluid supply of the drug to a level above the opening.

5. A transurethral device (10) for delivery of a drug into the urethra of a human or animal body comprising a drug carrying element (3) which presents an elongate shaft (9) having a free forward end for insertion into the urethra of the human or animal body in a forward direction, the elongate shaft being provided with a channel (15) having an opening (17) in the outer surface of the elongate shaft, and plunger means (5) adapted to move in the channel between a rearward position and a forward position characterised in that the device further comprises biasing means (30) for biasing the plunger means to the rearward position wherein the plunger means is movable forwardly from the rearward position to the forward position against the biasing action of the biasing means upon application of a predetermined condition to the plunger means and wherein removal of the predetermined condition after the plunger means has been moved forwardly from the rearward position against the biasing action of the biasing means causes the plunger means to be biased back to the rearward position by the biasing means whereby the drug is able to be drawn into the channel in the elongate shaft through the opening for transport of the drug into the urethra when the elongate shaft is dipped in a fluid supply of the drug to a level above the opening.

6. A transurethral device as claimed in claim 5, characterised in that the device further comprises a sheath (7) for sheathing at least the insertable length of the elongate shaft and that the fluid supply of the drug is contained in the sheath.

7. A transurethral device as claimed in claim 2, 3 or 6, characterised in that the fluid supply of drug in the sheath is so arranged in the sheath that at least a substantial portion of the outer surface of the insertable length of the elongate shaft is able to be coated with the drug prior to insertion into the urethra.

8. A transurethral device as claimed in claim 7, characterised in that the drug has lubricating properties so as to facilitate insertion of the elongate shaft into the urethra.

9. A transurethral device as claimed in claim 8, characterised in that the drug comprises the alfa-2 receptor antagonist Atipamezole, nitrates, long- and short-acting α blockers, calcium blockers, ergot alkaloids, chloropromazine, haloperidol, yohimbine, natural and synthetic vasoactive prostaglandins and their analogs, vasoactive intestinal peptides, dopamine agonists, opioid antagonists, sildenafil, prazosin, alprostadil or mixtures thereof where the device is to treat erectile dysfunction such as impotence

10. A transurethral device as claimed in claim 7, characterised in that the drug comprises a lubricant.

11. A transurethral device as claimed in claim 4, 5 or 6 or any one of claims 7, 8, 9 or 10 when appendant on claim 6, characterised in that the plunger means is movable forwardly against the biasing action of the biasing means on application of a predetermined force thereto.

12. A transurethral device as claimed in any one of the preceding claims, characterised in that the opening is a forward opening (17) in the free forward end of the elongate shaft, the drug carrying element has a rearward end and the channel extends between the forward opening and a rearward opening (19) in the rearward end of the drug carrying element.

13. A transurethral device as claimed in claim 12 when appendant on claim 4, 5 or 6, any one of claims 7, 8, 9 or 10 when appendant on claim 6, or claim 11, characterised in that the plunger means is a plunger element (5) which extends forwardly into the channel from the rearward opening.

14. A transurethral device as claimed in claim 13, characterised in that the channel is stepped into a forward section (16) of a first diameter which extends rearwardly from the forward opening and a rearward section (18) of a second diameter greater than the first diameter which extends forwardly from the rearward opening and the plunger element comprises a rearward section (25) adapted to slidingly fit in the rearward section of the channel such that in the rearward position of the plunger element the rearward end of the plunger element rearward section protrudes from the rearward opening of the channel and the forward end of the plunger element rearward section is disposed in the rearward section spaced rearwardly from the shoulder between the forward and rearward sections of the channel and a forward section (21) which extends forwardly from the forward end of the plunger element rearward section into the forward section of the channel.

15. A transurethral device as claimed in claim 14, characterised in that the biasing means is a resilient member (30) positioned between the forward end of the plunger element rearward section and the shoulder between the rearward and forward sections of the channel which is compressed on forward movement of the plunger element in the channel.

16. A transurethral device as claimed in claim 15, characterised in that the resilient member is a spring (30).

17. A transurethral device as claimed in claim 14, 15 or 16, characterised in that in the forward position of the plunger element the forward end of the plunger element rearward section abuts the shoulder between the rearward and forward sections.

18. A transurethral device as claimed in claim 14, 15 or 16, characterised in that in the forward position of the plunger element the forward end of the plunger element rearward section is prevented from any further appreciable forward movement by the resilient member.

19. A transurethral device as claimed in any one of claims 13 to 18, characterised in that forward movement of the plunger element against the biasing action of the biasing means when the drug has been drawn into the channel causes the drug to be ejected from the forward opening.

20. A method of incorporating a drug into a transurethral device for delivery of the drug to the urethra of a human or animal body, the transurethral device comprising a drug carrying element (3) which presents an elongate shaft (9) having a free forward end for insertion into the urethra of the human or animal body in a forward direction and a channel (15) having an opening (17) in the outer surface of the elongate shaft for transport of the drug to the urethra, characterised by the step of providing a fluid supply of the drug, dipping the elongate shaft into the fluid supply to a level above the opening of the channel and drawing a dose of the drug into the channel in the elongate shaft through the opening.

21. A method as claimed in claim 20, characterised in that the device is provided with means for drawing the dose of the drug into the channel from the fluid supply thereof.

22. A method as claimed in claim 20 or 21, characterised in that the transurethral device is a device according to any one of claims 1 to 19.

23. Use of a transurethral device as claimed in any one of claims 1 to 19 for the delivery of an erectile dysfunction treatment drug to the urethra of a living male human or animal body.

24. Use as claimed in claim 23 for the delivery of an impotence treatment drug.

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